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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tilmicosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for additions to labeling of tilmicosin for use in swine feed.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141–064 that provides for the use of PULMOTIL (tilmicosin phosphate) Type A medicated article in swine feed for the control of swine respiratory disease associated with certain bacterial organisms. The supplemental NADA provides for additional use information in labeling. The supplemental NADA is approved as of November 15, 2001, and the regulations are amended in 21 CFR 558.618 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.618 is amended by redesignating paragraphs (a) through (d) as paragraphs (b) through (e), respectively; by revising newly redesignated paragraphs (b), (c), and (e)(3) ~~and by~~ and by adding paragraph (a) to read as follows:

§ 558.618 Tilmicosin.

(a) *Specifications.* Type A medicated article containing 20 percent tilmicosin as tilmicosin phosphate (90.7 grams per pound).

(b) *Approvals.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Special considerations.* (1) Federal law limits this drug to use under the professional supervision of a licensed veterinarian. See § 558.6 of this chapter for additional requirements for the use of products regulated as veterinary feed directives (VFDs).

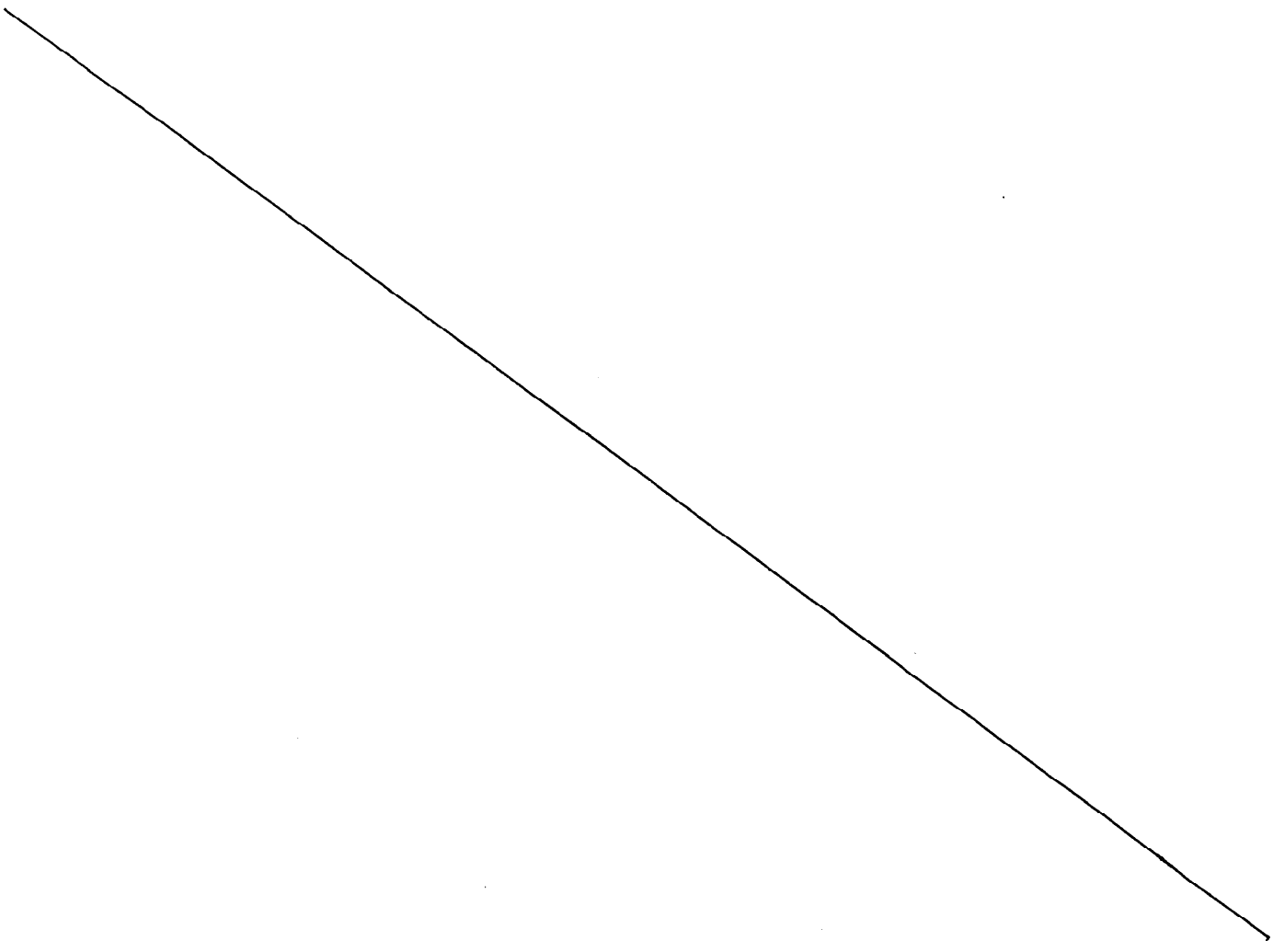
(2) The expiration date of VFDs for tilmicosin must not exceed 90 days from the time of issuance. VFDs for tilmicosin shall not be refilled.

(3) Do not use in Type B or Type C medicated feeds containing bentonite.

* * * * *

(e) * * *

(3) *Limitations.* Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an expected disease outbreak. Feed containing tilmicosin shall not be fed to pigs for more than 21 days during each phase of production without ceasing administration for reevaluation of antimicrobial use by a licensed veterinarian before reinitiating a further course



of therapy with an appropriate antimicrobial. The safety of tilmicosin has not been established in pregnant swine or swine intended for breeding purposes. Do not allow horses or other equines access to feeds containing tilmicosin. Withdraw 7 days before slaughter.

Dated: 4/9/02

April 9, 2002.

Andrew J. Beaulieu,
Acting Director,
Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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